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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,935	03/06/2002	Adi Shefer	4686-110 US	7056
7590 01/31/2007 Mathews, Collins, Shepherd & McKay, P.A. Suite 360 100 Thanet Circle Princeton, NJ 08540			EXAMINER GHALI, ISIS A D	
			ART UNIT 1615	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/31/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/091,935

Applicant(s)

SHEFER ET AL.

Examiner

Isis A. Ghali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,7-33,35,36,38-42 and 47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,7-33,35,36,38-42 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

The receipt is acknowledged of applicants' amendment filed 11/06/2006; and request for RCE filed 11/20/2006.

Claims 2, 3, 6, 34, 37, and 43-46 have been canceled.

Claims 1, 4, 5, 7-33, 35, 36, 38-42, and 47 are pending and included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/20/2006 has been entered.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

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obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1, 4, 5, 7-33, 35, 36, 38-42, and 47 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-50 of copending Application No. 10/376,736. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending applications and would be covered by any patent granted on the copending applications since the referenced copending applications and the instant application are claiming common subject matter as follows: the present claims and the conflicted copending claims are directed to patch and method of its use, wherein the patch comprises single matrix layer comprising bioadhesive water-soluble polymer selected from the group consisting of polyvinyl pyrrolidone (PVP), polyvinyl alcohol (PVA), modified starch derivatives, and hydrolyzed starches, and wherein the matrix dissolves or disintegrates in presence of water.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 4, 5, 7-33, 35, 36, 38-42, and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. Nowhere in the originally filed specification applicants disclosed that “the polymer matrix layer dissolves or disintegrates in the presence of water”. The specification disclosed the dissolution of the water soluble polymers in the polymer matrix which allows removal of the patch from the skin by rinsing, page 5, lines 20-22, i.e. only the water soluble component of the polymeric matrix dissolve in water and not the whole matrix disintegrates. The amendment made to the claims to recite “the patch is configured as a film for application onto the skin” has introduced new matter that is not described in the specification as originally filed. Applicants are referring to page 17, lines 17-20 for support, however, recourse to this text of the specification, applicants

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disclosed the patch is applied to area of skin to be treated after wetting, and not a patch configured as a film.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 4, 5, 7-33, 35, 36, 38-42, and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claims 1, 33, 35 and 42, the expressions "starch derivatives", "modified starch", "modified starch derivatives" do not set forth the metes and bounds of the claim. Recourse to the specification does not define the expressions in terms of what are the modified starches, derivatives of starch or derivatives of modified starch, that are suitable for practicing the present invention as matrix for a patch. The expression "phenoxy" in claim 7 and the expression "sorbitol derivatives" in claim 21 do not set forth the metes and bounds of the claims because the specification does not define the expressions.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1, 4, 5, 13-15, 17, 18, 21, 27, 29-33, 42, 47 are rejected under 35

U.S.C. 102(b) as being anticipated by 5,780,047 ('047).

The present claims 1 and 42 are directed to polymeric layer of film forming polymer selected from the group consisting of: maltodextrin, polyvinyl alcohol, polyvinyl pyrrolidone, modified starch derivatives, starch derivatives, modified starches, hydroxypropyl cellulose, and hydrolyzed starch and a combination thereof. Claims 33 and 35 are directed to method of using the polymeric layer.

US '047 disclosed patch comprises water-soluble adhesive sheet that can be applied to the skin and have adhesiveness such that it falls off from the skin upon wetting (abstract; col.2, lines 62-64; col.11, lines 13-15). The water-soluble polymers included polyvinyl pyrrolidone and pullulan, i.e. modified starch (col.3, lines 5-8). The adhesive sheet material further comprises glycerol and propylene glycol claimed by applicants in claim 21 as solubilizers (col.5, lines 4-12). The patch of polymer sheet further comprises active agents including drugs, vitamins, lanolin (moisturizer claimed by claims 14 and 15), vitamins, antiseptic, anti-inflammatory agent, sodium salicylate, amino acids, menthol and capsaicin (col.6, lines 59-64; col.7, lines 61-63; col.8, lines 7-10, 22; col.10, line 25). The adhesive sheet comprises fats and oils that read on permeation enhancer claimed by claim 17 (col.7, lines 38-52). The thickness of the water-soluble adhesive sheet is preferably from 20-1,000 μm , i.e. 0.02 to 1 mm as

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claimed by claim 29 (col.5, lines 29-33). The active ingredients are inherently uniformly distributed throughout the matrix as implied by the reference disclosure that the ingredients and the polymer matrix are mixed together (col.11, line 65).

10. Claims 1, 4, 5, 9, 10, 12, 14,15, 17, 18, 21-24, 27, 29-33, 42, 47 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,497,887 ('887).

The present claims 1 and 42 are directed to polymeric layer of film forming polymer selected from the group consisting of: maltodextrin, polyvinyl alcohol, polyvinyl pyrrolidone, modified starch derivatives, starch derivatives, modified starches, hydroxypropyl cellulose, and hydrolyzed starch and a combination thereof. Claims 33 and 35 are directed to method of using the polymeric layer.

US '887 disclosed polymeric membrane in form of matrix dissolvable upon wetting and can be used to deliver biologically active agents to the skin (abstract; col.3, line 45). The membrane permits sustained delivery of active ingredients to the skin and does not have to be peeled or washed off the skin, but simply dissolve (col.6, lines 11-16). The membrane is made of water-soluble polymers such as starches (col.1, lines 60-67; col.2, lines 21-34). The membrane further comprises additional film forming polymers such as hydroxypropyl cellulose and polyvinyl pyrrolidone and polyvinyl alcohols (col.3, lines 18-30). The active agents included in the membrane include moisturizers, salicylic acid, vitamins, whitening agents, antiseptics, anti-inflammatory agents, antihistamine, anti-aging agents, tanning agents (col.5, lines 10-20, 23-25, 33-40, 44, 59-67; col.6, lines 1-4). The membrane further comprises glycerin, that reads on

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solubilizers and permeation enhancers, and amino acids, that reads on claim 47 (col.3, lines 9-12). The membrane comprises polyphenols, i.e. antiseptic (col.6, line 26). The membrane may be wetted before use or applied to wetted skin (col.4, lines 63-67). The membrane has a thickness 0.1 to 1.5 mm and its shape and size are varied according to the intended use (col.3, lines 50-56). The active ingredients are inherently uniformly distributed throughout the matrix as implied by the reference disclosure that the ingredients and the polymer matrix are mixed together (col.6, line 47).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 7, 8, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '047 in view of US 2003/0027833 ('833).

The teachings of US '047 are discussed above. However, US '047 does not teach the specific antiseptics claimed by claims 7 and 10 and specific antibiotics claimed by claim 8.

US '833 discloses pharmaceutical composition in the form of single adhesive polymeric layer, film or matrix that deliver local anesthetic agent to the skin (abstract; page 2, paragraphs 0014-0017; page 9, paragraph 0091). The polymeric layer is water-soluble and can be removed easily by application of water, and selected from PVP, PVA, hydroxypropyl cellulose, starch and starch derivatives with a pharmaceutically active agent homogenously admixed therein with a permeation enhancer (page 2, paragraphs 0021, 0023; page 6, paragraph 0070, 71; page 7, paragraphs 0077, 0078). The polymeric layer further comprising additional active agent with the preferred additional active agents including bactericidal agent selected from iodine, silver, mercury compounds, phenol and chlorhexidine (page 4, paragraph 0051) and antibiotic including tetracycline (page 4, paragraph 0052).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide topical film of water soluble polymer to deliver active agents to the skin including antiseptic as disclosed by US '047, and select the antiseptic from iodine, silver, mercury compounds, phenol, chlorhexidine, and/or antibiotic including tetracycline as disclosed by US '833, motivated by the teaching of US '833

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that such antiseptics and antibiotics are preferred to be included in the matrices applied to the skin, with reasonable expectation of having topical film of water soluble polymer to deliver active agents to the skin including iodine, silver, mercury compounds, phenol, chlorhexidine, and/or tetracycline that delivers such ingredients to skin of the patient in need of such treatment wherein the film dissolves afterward without the need of the pain of peeling off of the film from the skin.

14. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '887 in view of US '883.

The teachings of the references are discussed above. However, US '887 does not teach the specific antiseptics claimed by claims 7 and specific antibiotics claimed by claim 8, that are taught by US '833.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide topical film of water soluble polymer to deliver active agents to the skin including antiseptic as disclosed by US '887, and select the antiseptic from iodine, silver, mercury compounds, chlorhexidine, and/or antibiotic including tetracycline as disclosed by US '833, motivated by the teaching of US '833 that such antiseptics and antibiotics are preferred to be included in the matrices applied to the skin, with reasonable expectation of having topical film of water soluble polymer to deliver active agents to the skin including iodine, silver, mercury compounds, chlorhexidine, and/or tetracycline that delivers such ingredients to skin of the patient in

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need of such treatment wherein the film dissolves afterward without the need of the pain of peeling off of the film from the skin.

15. Claims 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over any of US '047 or US '887.

The teachings of US '047 and US '887 are discussed above. However, the references do not teach the specific anti-inflammatory ibuprofen as claimed in claim 11 as an active agent.

It is within the skill in the art to determine the species of anti-inflammatory agent to be delivered to the skin by the water soluble polymer film disclosed by the references according to the specific patient need and intended use, since both references disclosed anti-inflammatory agent are suitable for delivery from such films. Applicants failed to show superior and unexpected results obtained by using the water-soluble film to deliver ibuprofen in particular. Therefore, ibuprofen claimed by claim 11 does not impart patentability to the claims, absent evidence to the contrary.

16. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over US '047 in view of US '887.

The teachings of US '047 and US '887 are discussed above. However, US '047 does not teach antihistamine as claimed in claim 12 that is taught by US '887.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide topical film of water soluble polymer to deliver active

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agents to the skin as disclosed by US '047, and replace the active agent by antihistamine as disclosed by US '887, motivated by the teaching of US '887 that such antihistamine can be delivered by dissolvable film, with reasonable expectation of having topical film of water soluble polymer to deliver antihistamine to the skin of the patient in need of such treatment wherein the film dissolves afterward without the need of the pain of peeling off of the film from the already compromised skin.

17. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over US '887 in view of US '047.

The teachings of US '887 and US '047 are discussed above. However, US '887 does not teach menthol or capsaicin as claimed in claim 13 that is taught by US '047.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide topical film of water soluble polymer to deliver active agents to the skin as disclosed by US '887, and add menthol or capsaicin as disclosed by US '047, motivated by the teaching of US '047 menthol provides cooling effect to the skin and capsaicin warming effect to the skin, with reasonable expectation of having topical film of water soluble polymer comprising menthol or capsaicin to provide cooling or warming effect to the skin according to the specific patient need and wherein the film dissolves afterward without the need of the pain of peeling off of the film from the skin.

18. Claims 9, 19, 20, 22-24, 26, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '047 in view of US 2001/0007671 ('671).

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The teachings of US '047 are discussed above.

However US '047 does not teach the salicylic acid as claimed in claim 9, the transparent polymeric film as claimed in claim 19 or colored as claimed in claim 20, the cosmetics claimed in claims 22-24, the effervescent claimed in claim 26, or the period of applying the film as claimed 35, and 36.

US '671 teaches a cosmetic, pharmaceutical, or dermatological patch for application of active agent to the skin (abstract; page 1, 0012, 0015). The patch imparts great softness, freshness and coolness and easily manipulated during application and removal from the skin (page 1, paragraph 0007). The patch includes a water-polymer matrix layer comprising an active agent and polymer (Figures 1; page 2, 0017, 0018, 0024, 0035; page 3, 0046; page 7, claim 15; page 8, claims 67-70). The active agents include moisturizers, bleaching agents (depigmentation agents), anti-acne agents, anti-aging agents, anti-wrinkle agents, anti-inflammatory agents, softeners, keratolytic agents, etc. (page 3, 0046, 0047). The patch is transparent or colored (page 2, 0020; page 3, 0050). The composition includes acetylsalicylic acid (aspirin) (page 3, 0047). The composition comprises sodium carbonate and sodium bicarbonate (page 3, 0043). The patch is applied to the skin from about few seconds to about few days (page 1, 0015). The composition further comprises salicylic acid, which is a keratolytic agent (page 3, 0048; page 8, claim 60).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide topical film of water soluble polymer to deliver active agents to the skin as disclosed by US '047, and add effervescent material and select

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the active agent suitable for delivery to the skin or across the skin according to the specific condition to be treated, and made the film colored or transparent and adjust the time of application of the film as disclosed by US '671, motivated by the teaching of US '671 that such ingredients when applied topically impart great softness, freshness and coolness to the skin, with reasonable expectation of delivering wide varieties of beneficial active agent to the skin from colored or transparent film for the desired period of time wherein the film dissolves afterward without the need of the pain of peeling off of the film from the skin.

19. Claims 19, 20, 26, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '887 in view of US '617.

The teachings of US '887 and US '617 are discussed above. However US '887 does not teach the transparent polymeric film as claimed in claim 19 or colored as claimed in claim 20, the effervescent claimed in claim 26, or the period of applying the film as claimed 35, and 36, which all taught by US '617.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide topical film of water soluble polymer to deliver active agents to the skin as disclosed by US '887, and add effervescent material, and made the film colored or transparent and adjust the time of application of the film as disclosed by US '671, motivated by the teaching of US '671 that such film when applied topically impart great softness, freshness and coolness to the skin, with reasonable expectation of delivering beneficial active agent to the skin for the desired period of time from

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colored of transparent film wherein the film dissolves afterward without the need of the pain of peeling off of the film from the skin.

20. Claims 25 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of US '047 or US '887, each in view of US 6,419,935 ('935).

The teachings of US '047 and US '887 are discussed above. However, US '047 and US '887 do not teach dihydroxyacetone claimed by claim 25 or the size of the film as claimed by claim 28.

US '935 teaches cosmetic skin treatment method includes providing a patch with good adhesiveness without drying the skin that includes polymeric matrix that includes at least one cosmetically active compound (abstract; col.1, lines 43-57; col.2, lines 49-57; col.9, lines 66-67). The patch is configured to adhere to the dry skin and to the moistened skin to provide treatment and cleansing the skin (abstract; col.2, lines 1-3, 57-59; col.3, lines 12-14). The patch provides treatment for time ranging from 5 minutes to 60 minutes (col.2, lines 8-12; col.4, lines 64-67). The cosmetically active compounds to be incorporated in the matrix include dihydroxyacetone (col.5, lines 62-65). The patches are cut to shapes designed to fit on various parts of the body and the preferred size ranges from 1 cm² to 30 cm² (col.9, lines 6-18). The polymeric matrix forms a layer having a thickness of 0.2 mm (col.9, lines 66-67).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide topical film of water soluble polymer to deliver active agents to the skin as disclosed by US '047 and US '887, and use the film to deliver

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dihydroxyacetone to the skin, and select the specific size of the film according to the area to be treated as disclosed by US '935, motivated by the teaching of US '935 that dihydroxyacetone is a tanning agent suitable for topical delivery from films and such a size of patch is suitable size, with reasonable expectation of delivering dihydroxyacetone to the skin from a film that dissolves afterward without the need of the pain of peeling off of the film from the skin.

21. Claims 16 and 38-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of US '047 and US '887, each in view of US 5,667,798 ('798).

The teachings of US '047 and US '887 are discussed above. However, the references do not teach microencapsulation of the active ingredients as claimed by claims 16, 38, 39 and 41, or their material as hydrophobic as claimed in claim 40.

US '798 teaches transdermal device comprises matrix comprising active agent dispersed in microencapsulated form to control the release of the active agents (abstract; col.1, line 67-col.2, line 2). The drug release into the matrix is controlled by selecting the microcapsules as hydrophilic or hydrophobic (col.2, lines 9-15).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide topical film of water soluble polymer to deliver active agents to the skin as disclosed by US '047 and US '887, and further microencapsulate the active agent in hydrophobic material as disclosed by US '798, motivated by the teaching of US '798 that microcapsules and their material play role in controlling the release of the active agent, with reasonable expectation of having topical film of water

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soluble polymer comprising microencapsulated active agents to be delivered to the skin of the used in a controlled release manner effectively.

Response to Arguments

22. Applicant's arguments with respect to claims 1, 4, 5, 7-33, 35, 36, 38-42, and 47 have been considered but are moot in view of the new ground(s) of rejection.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

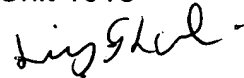
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Isis A Ghali
Primary Examiner
Art Unit 1615



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